

8

Docket No. UF-267XC1
Serial No. 10/080,772Remarks

Claims 1-46 are pending in the subject application. By this Amendment, Applicants have amended claims 5, 12, 22, 25, 27, 40, and 45, and canceled claims 29-35. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1-28 and 36-46 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Submitted with this Amendment is a Supplemental Information Disclosure Statement (IDS) for the Examiner's consideration. Applicants respectfully request that the references in the IDS be made of record in the subject application.

As an initial matter, Applicants gratefully acknowledge the Examiner's indication in the outstanding Office Action that the rejection of claims 1-21, 29-39, and 41-46 under 35 USC §103(a) as obvious over published PCT application WO 94/02613 has been withdrawn. Applicants also gratefully acknowledge the Examiner's indication that claims 6-14, 36-39, and 43-46 have been allowed in the subject application.

Claims 22-28 and 40 remain rejected under 35 USC §103(a) as obvious over published PCT application WO 94/02613. By this Amendment, Applicants have amended claims 22, 25, 27, and 40 to recite that the animal is a "non-feline" animal. Applicants respectfully assert that this amendment of the claims obviates the rejection. Accordingly, reconsideration and withdrawal of the rejection under 35 USC 103(a) is respectfully requested.

Claims 15-35 are rejected under 35 USC §112, first paragraph, as nonenabled by the subject specification. While acknowledging that the specification does enable a method for inducing an immune response to FIV or HIV, the Examiner asserts the specification does not reasonably provide enablement for a method for treating or preventing FIV or HIV infection in a human or a non-feline animal. Applicants respectfully assert that the claims are enabled by the subject specification. However, by this Amendment, Applicants have canceled claims 29-35, which are directed to methods for treating or preventing HIV infection in a human or non-feline animal. Accordingly, the rejection of claims 29-35 is moot.

Applicants respectfully submit that pending claims 15-28, which are directed to methods for treating or preventing FIV infection in a human or non-feline animal by administering an FIV

I:\src\ptc\Amd\UF-267XC1.2d.doc/DNB/sl

immunogen, are enabled by the subject specification. It is known in the art that the administration of FIV immunogens can prevent FIV infection in cats (see, for example, U.S. Patent Nos. 5,037,753, 5,118,602, 5,275,813, 5,510,106, and 6,107,077). There is also a commercially available FIV-immunogen based vaccine approved for cats (Fel-O-Vax FIV[®], Fort Dodge Animal Health). It is also accepted in the art that in those cases where a virus or bacteria is known to infect more than one species of animal, that a vaccine that is effective in preventing infection by the virus or bacteria in one of the infectable species can also be effective in preventing infection in other animal species the virus is capable of infecting. For example, Rabvac-3[™] (Fort Dodge Animal Health) is a single commercial vaccine product that is approved and marketed for immunizing dogs, cats, and horses to protect these animals against infection by rabies virus. In another example, the same tetanus toxoid is used to immunize cattle, sheep, goats, horses, and swine. In a further example, Ultrabac[®] 7, Ultrabac[®] 8, and Electroid[®] 7 (Pfizer and Schering-Plough) are commercial vaccine products approved and marketed for immunizing both sheep and cattle. Therefore, a person of ordinary skill in the art, having the benefit of the teachings of the subject application, would reasonably expect that the administration of FIV immunogens to humans or non-feline animals would be effective at treating or preventing FIV infection in those humans or non-feline animals. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

Claims 1-4 are rejected under 35 USC §102(a) as anticipated by Johnston *et al.* (2001) and claims 1-5, 15-18, and 40-42 are rejected under 35 USC §103(a) as obvious over Johnston *et al.* (2001). The Examiner states that the Johnston *et al.* publication teaches a method for inducing an immune response to a FIV in a non-feline animal, *i.e.*, macaques. The Examiner further states that the Johnston *et al.* publication discloses detection of FIV-specific sequences in PBMC and anti-FIV antibodies in sera from infected macaques. The Examiner asserts that, in view of the teachings of the cited reference, it would have been obvious for an ordinarily skilled artisan to immunize a non-feline animal against FIV infection by using an FIV immunogen. Applicants respectfully traverse these grounds of rejection.

Applicants respectfully assert that the Johnston *et al.* reference is not available as a reference under §102/103 against the subject application. Applicants note that the subject application claims

10

Docket No. UF-267XC1
Serial No. 10/080,772

the benefit of provisional Application No. 60/270,745 (hereinafter the '745 application), filed February 22, 2001. The '745 provisional application discloses the invention being claimed in the subject application. The Johnston *et al.* reference appears to have been published sometime in July 2001 (the reference itself lists July 24, 2001 as the publication date). Thus, the subject application, which is entitled to the filing date of the '745 provisional application (February 22, 2001), has an effective filing date that is approximately six months prior to the indicated publication date of the Johnston *et al.* reference (July 24, 2001). The Johnston *et al.* (2001) reference is, therefore, not effective prior art against the subject application. Accordingly, reconsideration and withdrawal of the rejections under 35 USC §102(a) and §103(a) is respectfully requested.


It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Doran R. Pace
Patent Attorney
Registration No. 38,261
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: 2421 N.W. 41st Street, Suite A-1
Gainesville, FL 32606-6669

DRP/sl

Attachment: Supplemental Information Disclosure Statement

II:\doc\pio\Amd\UF-267XC1.2d doc\DNB/sl